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Subject: Review of "Title 17 Re-draft No. 2"

The Office of Regulations (OOR) in the California Department of Health Services (CDHS) has conducted a limited review of the draft regulations for the Forensic Alcohol Review Committee (FARC) entitled "Title 17 Re-draft No. 2." This review memorandum and attached notated version of the draft regulations has been prepared for the review and consideration of FARC.

As FARC was informed, the Administrative Procedures Act (APA) governs the regulatory process in the State of California. Not only does this statute prohibit the arbitrary imposition of requirements on the public, the process also attempts to establish fundamental standards for all regulations promulgated by state agencies within the State of California. It is these standards that the Office of Administrative Law (OAL) reviews in their determination of approval or disapproval of the proposed regulations. The standards of the APA are: Authority, Reference, Clarity, Necessity, Consistency, and Non-duplication. The following review addresses those standards as they relate to the drafted proposed regulations.

This review also takes into account the opinion received from OAL on January 24, 2007 that, because of the specific language of SB 1623 that requires FARC to "evaluate" current Forensic Alcohol Laboratory (FAL) regulations in Title 17 of the California Code of Regulations (CCR) and "determine revisions that will *limit* those regulations to those that the review committee determines are *reasonably necessary* to ensure the competence of the laboratories and employees…" (H&S Code §100703(d), emphasis added), it is necessary for FARC to state within the rulemaking file the "rationale/reasonable necessity" for each provision in current regulation that FARC chooses to retain. This opinion arose from a question posed by OOR based on experience engendered with a somewhat similarly worded statute being interpreted, implemented and made more specific by another CDHS program in regulation. That program experienced the disapproval of its proposed regulations by OAL because of the failure of that program to

explain the “rationale/reasonable necessity” within the rulemaking file for all retained provisions in the current regulations that were specified in the statute. With this experience, OOR asked if the same unusual requirement applied to the promulgation of the FAL regulations and was informed by the reference attorney at OAL that it was his opinion that it did, because the statute required the committee to review and limit the current regulations. This statement demonstrating the necessity for the retention of current regulatory provisions was determined by the reference attorney to be a reasonable expectation of the promulgating committee, even though it is beyond the usual requirements of the APA.

Upon consideration of this opinion from the OAL reference attorney, OOR determined it is necessary to recommend to FARC that the proposed FAL regulations that it is drafting include within the rulemaking file in a location where the necessity for all amendments, adoptions and repeals is traditionally demonstrated to meet the necessity standard of the APA, that is, within the text of the Initial Statement of Reasons (ISOR), a statement that demonstrates that FARC reviewed all the current regulations and determined those retained to be only those necessary to ensure the competence of the laboratories and employees. This statement will also need to then demonstrate for each retained provision rationale/reasonable necessity that indeed the retained provision helps to ensure competency of the laboratories or employees.

Since it is assumed that FARC will determine it wishes to make the recommended statement that the retained provisions are necessary to “ensure the competence of the laboratories and employees,” it is reasoned that the retained provisions will be those FARC holds necessary to ensure competence and statements will be possible to make in the ISOR that provide the rationale on which FARC based this determination for each provision. These statements could be evidence that demonstrates that the provisions are the national or professional standards, or are from some other such “expert” source, or even a statement that the experience of the FAL program in enforcing the retained provisions helped maintain the competence of laboratories and employees in some specified manner. However, if the provision is to be retained as currently worded it will need to be reasonably defensible to the regulated public as a standard that is necessary to ensure competence. The regulated public will have the opportunity to comment on the proposed regulations and those comments will not be limited to the amendments, adoptions, or repeals, but may include comment on the retained text if the commenter desires to so comment. FARC will need to respond to all comments and that response will need to address whatever issue the commenter makes.

As offered by OOR in the past, portions of the current regulation text appear to have more than one interpretation. To meet the requirement of clarity, the regulation text, whether it is new text or retained text, should be clear and have

only one interpretation that is obvious to all, so that laboratories can easily understand the standards and what is required of them.

OOR considers that it is possible to argue that the repeals of all the licensing provisions within current regulation are “Rule 100” changes due to the statutory repeal of licensing of the FALs in SB1623. However, the justification that will need to be made will need to include language that speaks to FARC having determined that the only pre-SB 1623 role for CDHS was licensing and that CDHS has no other role that is necessary to ensure the competence of the laboratories and employees. FARC will need to make this determination in order to make the argument that the repeals are simply Rule 100 changes. Therefore, FARC may not be able to argue that deletions of reference to the Department that are not related to licensing are Rule 100 changes.It is possible and reasonable for FARC to propose some role that does not involve licensing for CDHS that may include course approvals, personnel qualification approvals, or some other activities that FARC may determine are necessary to ensure competence if FARC so specifies. If FARC makes this determination for CDHS, then the proposed role will need to be stated in regulation and the necessity demonstrated in the ISOR. The repeals of the specific licensing language will continue to be a Rule 100 change; however, the ability to apply this rationale as broadly as suggested in the comment notes appended to the re-draft will be more limited and other reasoning will need to be applied to support the other repeals.

It is the intent of OOR’s comments and suggested amendments made in the re-draft document to assist in making the current regulatory provision clearer such that there is only one interpretation of the provision if that provision is to be retained. FARC will find that OOR frequently cites the amendments proposed in the redraft of the regulation text dated January 5, 2006. The reason for this citation is to prevent duplication of the work already conducted by OOR in light of the significant increase in workload for OOR that is the case due to the reorganization of CDHS into the California Department of Public Health (DPH) and California Department of Health Care Services (DHCS) on July 1, 2007. The committee may determine other language if it desires or may repeal any provision it does not see as necessary to ensure competence. All suggested amendments made to the retained text by OOR are provided in blue with amendments documented in single underline and repeals in strikeout. OOR comments in the comments section are noted as such and are not in colored text because the previous reviewers for the subcommittee used colors and confusion would occur with the use of colored text by OOR.

FARC is also asked to determine the mechanisms it wishes to use to pursue the necessary further steps in regulation promulgation once FARC has committed to proposed regulation text. The further steps are:

1. Write the final draft of the proposed regulation text in printer's instruction format of underline and strikeout with redesignation of text as needed and to include authority and reference citations.

2. Write the Initial Statement of Reasons.

3. Write the other supporting documents to include the Informative Digest, Statements of Determinations, Fiscal Impact Estimate, and Reference List.

4. Obtain all reference documents in duplicate and obtain any copy-write releases that are necessary to utilize the documents if they are not readily accessible to the public.

5. Formally approve as a committee the proposed regulation package that will be submitted to Health and Human Services Agency (HHSA).

6. Submit the package to HHSA for review and disapproval of provisions as required in H&S Code §100703(d).

7. Redraft of all documents based on outcome of HHSA's review.

8. Submit the package for formal processing through CDHS or its successor, DPH, HHSA, and Department of Finance, as fiscal impact to the State of California is anticipated.

FARC is also asked to determine the mechanisms it wishes to use to complete the public processes for promulgation of its regulations. These public processes are:

1. Specify the FARC contact for public notice.

2. Specify if a public hearing will be held for public comment on the noticed package. Specify the scope of the mailing of the public notice.

3. Consider and write the responses to public comment.

4. Determine regulatory changes based on public comment. If regulatory changes are made, resubmit those changes to HHSA for disapproval and renotice the package for 15-day public comment and complete the written responses to comments received in that process.

5. Formally review and approve the package as complete for filing.

6. Submit the package for filing with OAL to CDHS or its successor, DPH.

FARC is asked to please understand that the suggestions and comments offered in this review are simply those of OOR and in no way propose to be the only and

definitive answer to the means to stipulate any provisions in regulation. All OOR suggestions are based on knowledge gained from extensive experience in promulgating regulation for the many and diverse programs in CDHS, but as is always the case, there are multiple ways to write regulation and still meet the standards of the APA. OOR has found that some methodologies for regulation writing are more likely to succeed with minimal difficulties as they proceed through the process, while others pose significantly greater difficulty for the writers during the public process and have greater risk of ultimately failing. It is entirely up to FARC to determine the course it wishes to take in writing the FAL regulations. OOR simply offers the risks it has learned from experience and does not in any way wish to propose that it is requiring FARC to adopt, amend, or repeal any provision. OOR is simply a consulting body and has absolutely no opinions on what FARC decides to promulgate or how FARC decides to complete its work.

OOR truly appreciates the effort the FARC subcommittee invested in this re-draft of the FAL regulations. OOR looks forward to continuing to work with FARC to further this process and see it to a satisfactory and successful conclusion. Should you have any questions, please feel free to contact me at (916) 440-7841.

cc: Goldie Eng, Senior Staff Counsel
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